AMENDED IN ASSEMBLY JULY 10, 1997

AMENDED IN SENATE MAY 22, 1997

SENATE BILL No. 625

Introduced by Senator Rosenthal

February 25, 1997

An act to add ~~Section 1367.20~~ *Sections 1367.20 and 1367.24* to the Health and Safety Code, relating to health care service plans.

LEGISLATIVE COUNSEL'S DIGEST

SB 625, as amended, Rosenthal. Health care service plans: drugs.

Existing law provides for the licensure and regulation of health care service plans by the Department of Corporations, and provides that a willful violation of its provisions is subject to criminal sanction. Existing law imposes various requirements and restrictions on health care service plans including, among other things, a prohibition on health care service plans that provide prescription drug benefits from excluding or limiting coverage for a drug on the basis that the drug is prescribed for a use that is different from the use for which the drug has been approved for marketing by the federal Food and Drug Administration.

This bill would require a health care service plan that provides prescription drug benefits ~~to, among other things, submit to the department its complete formulary, a list of prescription drugs on the formulary, and a statement describing whether the formulary is an open or closed~~

~~formulary, maintain an efficient and timely process, disclosed to enrollees, by which a physician may request a nonformulary drug or nonpreferred drug, and use an independent Pharmacy and Therapeutic Committee to develop and oversee its formulary. It would also impose certain requirements with regard to disclosure of incentives associated with the use of any of the drugs on the formulary and incentives for drug switching.~~

~~The bill would also require the department to investigate whether any pharmaceutical benefit managers operating in California meet the definition of a health care service plan, and to report its findings to the Legislature no later than July 1, 1998~~ *and maintains one or more drug formularies to provide to members of the public, upon request, a copy of the most current list of prescription drugs on the formulary by major therapeutic category.*

The bill would require every health care service plan that provides prescription drug benefits to maintain an expeditious process by which prescribing providers, as described, may obtain authorization for a medically necessary nonformulary prescription drug, according to certain procedures.

The bill would prohibit certain of its provisions from having any effect unless AB 974 takes effect on or before January 1, 1998, and adds a particular provision.

By imposing these requirements on health care service plans, this bill would change the definition of a crime, thereby imposing a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 1367.20 is added to the Health and Safety Code, to read:

1367.20. ~~(a)~~ Every health care service plan that ~~provides prescription drug benefits shall do all of the following:~~

~~(1) Submit to the commissioner on an annual basis the complete formulary of the plan, if the plan maintains a formulary, a list of the prescription drugs on the formulary of the plan that indicates any drugs that are preferred over other drugs on the formulary, and a statement describing whether the formulary is an open or closed formulary. Each plan shall provide copies of the list of prescription drugs on a formulary of the plan to members of the public upon request.~~

~~(2) Maintain an efficient and timely process, which shall be described to enrollees in evidence of coverage and disclosure forms, by which participating physicians may request coverage for a medically necessary nonformulary prescription drug or nonpreferred formulary drug that provides for all of the following:~~

~~(A) The plan may require the physician, except in cases covered by the continuity of care drug therapy regimen provisions of Section 1367.22, to provide the medical reasons supporting the use by the enrollee of a nonformulary or nonpreferred formulary drug.~~

~~(B) Requests by physicians for coverage of a nonformulary or nonpreferred formulary drug shall be approved or disapproved by the plan within two working days of receipt by the plan of the request of the physician, unless the plan within the two-day period requests additional information regarding the medical condition of the enrollee from the treating physician, in which case the plan shall approve or disapprove the request within two working days of receipt of the additional information from the physician.~~

~~(C) Any disapproval of a request by a physician for coverage of a nonformulary or nonpreferred formulary drug shall provide the reasons for the disapproval and~~

~~provide an alternative drug or drugs, or alternative treatment when appropriate, that will be covered by the plan, and meets the medical needs of the enrollee, as indicated by the treating physician.~~

~~(D) Any plan disapproval of a request by a physician for coverage of a nonformulary or nonpreferred formulary drug shall be concurrently sent to the enrollee and shall be accompanied by a statement that the enrollee may file a grievance with the plan, and a complaint with the department, in cases involving an imminent and serious threat to the health of the enrollee or after the enrollee has either completed the grievance process of the plan or participated in the process for at least 60 days. This notice shall include the toll-free telephone number of the department specified in Section 1368.02.~~

~~(3) Use a Pharmacy and Therapeutic (P&T) Committee to develop and oversee its formulary. The composition of the committee, along with any changes in composition, shall be reported annually to the commissioner. The commissioner shall keep the names of the members of each committee confidential. The committee shall keep records that fully describe the reasoning behind formulary decisions, and these records shall be submitted to the commissioner annually.~~

~~(4) Disclose to the commissioner on an annual basis both of the following:~~

~~(A) Any financial incentives to the plan associated with the use of any of the drugs listed on the formulary of the plan.~~

~~(B) Any bonus or incentive arrangements to physicians, pharmacists, or contracting pharmaceutical benefit management companies, including any bonuses or incentives provided as part of any therapeutic drug switching program used by a plan, that are associated with activities of the plan to encourage formulary compliance.~~

~~(b) The department shall review the information submitted pursuant to subdivision (a) as warranted to ensure plan compliance with this article, including~~

~~compliance with subdivision (g) of Section 1367, which requires each plan to demonstrate that medical decisions are to be rendered by qualified medical providers, unhindered by fiscal and administrative management. In addition, the department shall ensure compliance with this section as part of its periodic onsite medical survey of each plan undertaken pursuant to Section 1380, and shall include a discussion of compliance with this section as part of its report issued pursuant to Section 1380.~~

~~(c) As part of any therapeutic drug switching program implemented by a plan directly or by contract that is used to encourage formulary compliance, the plan shall require pharmacists to disclose to the enrollee at the time of a recommended drug switch any health risks associated with the switch.~~

~~(d) The department shall investigate whether any pharmaceutical benefit management companies operating in California meet the definition of a "health care service plan" in subdivision (f) of Section 1345 or a "specialized health care service plan contract" in subdivision (o) of Section 1345, and whether any pharmaceutical benefit management companies are subject to licensure pursuant to Section 1349. The department shall report the results of that investigation to the Legislature no later than July 1, 1998.~~

~~(e) Nothing in this section shall be construed to require the department to disclose trade secrets, commercial or financial information, or other proprietary information that is privileged or confidential, as determined by the commissioner.~~

~~SEC. 2. The reference to the continuity of care drug therapy regimen provisions of paragraph (2) of subdivision (a) of Section 1367.20 of the Health and Safety Code as set forth in Section 1 of this bill shall have no effect unless Section 1367.22 of the Health and Safety Code, as added by Assembly Bill 974 of the 1997–98 Regular Session, takes effect on or before January 1, 1998.~~

~~SEC. 3.~~ *provides prescription drug benefits and maintains one or more drug formularies shall provide to members of the public, upon request, a copy of the most*

current list of prescription drugs on the formulary of the plan by major therapeutic category, with an indication of whether any drugs on the list are preferred over other listed drugs. If the health care service plan maintains more than one formulary, the plan shall notify the requester that a choice of formulary lists is available.

SEC. 2. Section 1367.24 is added to the Health and Safety Code, to read:

1367.24. (a) Every health care service plan that provides prescription drug benefits shall maintain an expeditious process by which prescribing providers may obtain authorization for a medically necessary nonformulary prescription drug. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription, pursuant to Section 4059 of the Business and Professions Code, to treat a medical condition of an enrollee.

(b) Any plan disapproval of a request by a prescribing provider to obtain authorization for a nonformulary drug shall provide the reasons for the disapproval.

(c) A notice of plan disapproval issued pursuant to subdivision (b) shall be sent to the enrollee and shall be accompanied by a statement that the enrollee may file a grievance with the plan if the enrollee objects to the reasons for the disapproval. The notice shall comply with subdivision (b) of Section 1368.02.

(d) The process described in subdivision (a) by which prescribing providers may obtain authorization for medically necessary nonformulary drugs shall not apply to a nonformulary drug that has been prescribed for an enrollee in conformance with the continuity of care drug therapy regimen provisions of Section 1367.22.

(e) The process described in subdivision (a) by which prescribing providers may obtain authorization for medically necessary nonformulary drugs shall be described in disclosure forms, as required by subdivision (a) of Section 1363, issued on or after July 1, 1998.

(f) Every health care service plan that provides prescription drug benefits shall maintain, as part of its books and records under Section 1381, all of the following

information, which shall be made available to the commissioner upon request:

(1) The complete drug formulary or formularies of the plan, if the plan maintains a formulary, including a list of the prescription drugs on the formulary of the plan by major therapeutic category with an indication of whether any drugs are preferred over other drugs.

(2) Records developed by the Pharmacy and Therapeutic Committee of the plan, or by others responsible for developing, modifying, and overseeing formularies used to guide the drugs prescribed for the enrollees of the plan, that fully describe the reasoning behind formulary decisions.

(3) Any plan arrangements with physicians, medical groups, individual practice associations, pharmacists, or contracting pharmaceutical benefit management companies that are associated with activities of the plan to encourage formulary compliance or otherwise manage prescription drug benefits.

(g) If a plan provides prescription drug benefits, the department shall, as part of its periodic onsite medical survey of each plan undertaken pursuant to Section 1380, review the procedures and information maintained pursuant to this section and describe the plan's performance as part of its report issued pursuant to Section 1380.

(h) The commissioner shall not publicly disclose any information reviewed pursuant to this section that is determined by the commissioner to be confidential pursuant to state law.

(i) Nothing in this section shall be construed to restrict or impair the application of any other provision of this chapter, including, but not limited to, Section 1367.

SEC. 3. The reference to the continuity of care drug therapy regimen provisions of subdivision (d) of Section 1367.24 of the Health and Safety Code as set forth in Section 2 of this bill shall have no effect unless Section 1367.22 of the Health and Safety Code, as added by Assembly Bill 974 of the 1997–98 Regular Session, takes effect on or before January 1, 1998.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Notwithstanding Section 17580 of the Government Code, unless otherwise specified, the provisions of this act shall become operative on the same date that the act takes effect pursuant to the California Constitution.

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